UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,784	01/08/2002	Kjell Olmarker	003300-872	8785

21839 7590 04/30/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,784	OLMARKER ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *2-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 are pending.

1. Applicant's election with traverse of Group I claim 1 in response to restriction requirement filed on 03/10/2004 is acknowledged. The traversal is on the ground(s) that there is a technical relationship between each of the groups. This is not found persuasive because the inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is considered to be a kit for diagnosing disc herniation, comprising antigens from nucleus pulposus cells. The special technical feature of Group II is considered to be a method for treatment disc herniation comprising administering *an anti-antibody to antibodies* of nucleus pulposus cells. The special technical feature of Group III is considered to be a method for treatment disc herniation comprising administering *false antibody* to nucleus pulposus cells. The special technical feature of Group IV is considered to be a method for treatment disc herniation comprising administering a *soluble antigens* from nucleus pulposus cells. The special technical feature of Group V is considered to be a method for the diagnosis of disc herniation comprising administering a *soluble antigens* from nucleus pulposus cells. The special technical feature of Group VI is considered to be a method for treatment disc herniation comprising administering a *compound* that prevents the binding of serum antibodies to nucleus pulposus cells to bind to nucleus pulposus.

Accordingly, Groups I-VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-8 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claim 1 read on a kit for diagnosing disc herniation, comprising antigens from nucleus pulposus cells under consideration in the instant application.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and ambiguous in the recitation of " antigens from nucleus pulposus cells for determining the presence of antibodies to nucleus pulposus". It is unclear how can antigen from nucleus pulposus cells can be used to detect antibodies to nucleus pulposus. The specification on page 1 define "nucleus pulposus as the viscous component of the intervertebral disc that leaks out of the spinal canal". It is unclear if nucleus pulposus comprises nucleus pulposus cells ?

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

(A) The claims as written encompass the genus of antigens from nucleus pulposus cells . The genus encompasses peptides wherein such peptides have numerous differences in amino acid sequences which are not even disclosed.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification does not provide a sufficient enabling description of the claimed invention. A person of skill in the art is not enabled to make and use any antigens from nucleus pulposus cells as recited in the claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. Applicant has not taught any antigens from nucleus pulposus cells that can be used in a kit for diagnosing disc herniation. Applicant has not taught how to make and/or use any antigens from nucleus pulposus cells. The structural and functional characteristics of said antigens are not defined in the claim. One cannot extrapolate the teachings of the specification to the scope of the claims because the claim is drawn a kit for diagnosing disc herniation comprising antigens from nucleus pulposus cells however, the Specifications does not show or define any antigens from nucleus pulposus cells that can be used for diagnosing disc herniation. Applicant has not enabled structurally related and unrelated any antigens from nucleus pulposus cells to be used in a kit for diagnosing disc herniation. Without sufficient guidance, the changes which can be made in the structure of any "antigens from nucleus pulposus cells and still provide or maintain sufficient or the claimed activity is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Applicant has not provided sufficient biochemical information (e.g. structural characteristics, amino acid composition , physicochemical properties, etc) that distinctly identifies such "antigens from nucleus pulposus cells that can be used in a kit for determining the presence of antibodies to nucleus pulposus. While any "antigens from nucleus pulposus cells " may have some notion of the activity of the "antigens", for determining the presence of antibodies to nucleus pulposus, claiming biochemical molecules by such properties fails to provide sufficient guidance and direction as to how the skilled artisan can make such agents, commensurate in scope with the claimed invention. Since the instant fact pattern fails to indicate that representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claims and consequently would not know how to make them.

Applicant is relying upon certain biological activities and however there is no teaching of any antigens from nucleus pulposus cells to support an entire genus. It is well known that minor structural differences among even structurally related compounds or compositions can result in substantially different biology, expression, and pharmacology of proteins. Moreover, Applicant himself acknowledge that there may be a lack of sensitizing antigens in the disc cells. Therefore, structurally unrelated any antigens from nucleus pulposus cells would be expected to have greater differences in their activities.

Also the issue is that applicant has not exemplified *in vitro* studies or in animal models studies that shows the use of a kit comprising any antigens from nucleus pulposus cells to diagnosing disc herniation. Moreover, Applicant himself acknowledge that inactive disc herniation is a mere protrusion of disc tissue without triggering of the immune system. Applicant further disclosed that the lack of immunologic reaction might be based on lack of sensitizing antigens in the disc cells. (see page 5 lines 15 20 of the Specification as filed). It is unclear how one can use a kit for diagnosing disc herniation, comprising antigens from nucleus pulposus cells for determining the presence of antibodies if there is no immune response and thus no antibodies?

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed kit for diagnosing disc herniation, comprising any antigens from nucleus pulposus cells in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of : kit for diagnosing disc herniation, comprising any antigens from nucleus pulposus cells.

The specification fails to define any antigens from nucleus pulposus cells that can be used in a kit for diagnosing disc herniation. There is no description of an actual reduction to practice, each step of the claimed kit for diagnosing disc herniation or distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. Applicant has not disclosed any antigen from nucleus pulposus cells that can be used in a kit for diagnosing disc herniation ; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention.

The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

A description of what a material does rather than of what it is, usually does not suffice. The patent does not more than describe the desired function of the compound called for and contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. Inadequate written description that merely identifies a plan to accomplish an intended result "is an attempt to preempt the future before it has arrived" *Fiers v. Revel*, 984 F.2d 1164,1171 9Fed.Cir. 1993).

A description of a genus of antigens sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).
Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 rejected under 35 U.S.C. 102(a) as being anticipated by WO 98/41865 as evidenced by Satoch et al (IDS).

WO' 865 teaches a kit to detect autoantibodies towards collagen type II, comprising antigen of mammalian type II collagen. As is evidenced by Satoch et al., collagen is a major component and antigen of nucleus pulposus cells (see page 1984 in particular). The recited "antigens from nucleu pulposus cells" in the instant claim 1 reads on the collagen antigen . Thus referenced kit can be inherently used for diagnosing disc herniation.

The reference teaching anticipates the claimed invention.

9. Claim 1 rejected under 35 U.S.C. 102(b) as being anticipated by WO 94/14070 as evidenced by Satoch et al (IDS).

WO' 070 teaches a kit to determining the presence of autoantibodies towards collagen. (see entire document Abstract and pages 11 and 18 in particular. As is evidenced by Satoch et al., collagen is a major component and antigen of nucleus pulposus cells (see page 1984 in particular). The recited "antigens from nucleu pulposus cells" in the instant claim 1 reads on the collagen antigen . Thus referenced kit can be inherently used for diagnosing disc herniation.

The reference teaching anticipates the claimed invention.

10. No claim is allowed.

11. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
April 28, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600